REMARKS/ARGUMENTS

Applicants have not dedicated or abandoned any unclaimed subject matter and have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Status of the Claims

Claims 1-47 and 62 are canceled. Claims 48-60 are withdrawn from consideration. As such, claims 61 and 63-73 are currently under consideration in this application.

Claim 61 is amended to clarify that the first conjugate comprises "a first marker molecule and a first protein", which is supported throughout the specification, for example, in paragraphs [0055] through [0060] of the published application. Claim 61 is further amended to clarify that the first protein of the first conjugate is "associated with the desensitization pathway of said first GPCR", which is supported, for example, in paragraphs [0058] through [0060]. These amendments are thus fully supported by the specification and add no new matter.

Claims 63-65 are amended to clarify that the first or second marker molecule may be one of the recited molecules. As such, these amendments add no new matter.

Claims 67-68 are amended to clarify the proteins of the conjugates recited in claim 61. As such, these amendments add no new matter.

Applicants respectfully request entry of the claims as amended.

Elections/restrictions

The Office Action states on page 2 that claims 48 to 72 are withdrawn from further consideration as being drawn to a non-elected invention. Applicants note that only claims 48-60 are withdrawn from consideration – claims 61 through 72 read on the elected invention, as is stated on the Office Action Summary (Form PTOL-326). Applicants presume that the statement on page 2 of the Office Action is a typographical error and should state claims 48 to 60 are withdrawn from consideration.

Drawings

The attached sheets of replacement drawings include changes to Figures 2 and 3 (total of 7 sheets). Figures 2 and 3 have been renumbered in compliance with 37 C.F.R § 1.84(U)(1). No new matter is added by these changes, and Applicants respectfully request entry of the corrected drawings.

Specification

The Office Action states on page 3 that the specification requires a reference to a particular sequence identifier to be in compliance with 37 C.F.R. §1.821(d). The Office Action further states that the amino acid sequence "NPXXY" is referred to throughout the specification without employing a sequence identifier. Applicants respectfully submit that the amino acid sequence NPXXY does not require a sequence identifier. 37 CFR 1.821(a) states that "Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. The amino acid sequence "NPXXY" has fewer than four specifically defined amino acids, and thus a sequence identifier is not required.

The sequence identifier for "TTIST" on page 16 line 4 is included in the substitute specification submitted with this response. Applicants respectfully submit that all objections to the specification are now most and may be withdrawn.

Rejections under 35 USC § 112

Claims 61 to 66 and 68 to 73 are rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the written description and enablement requirements. Applicants respectfully disagree.

The Office Action asserts that the only compound described in the instant specification or the art of record that is capable of functioning in the context of the instant invention is an arrestin protein. Applicants respectfully submit that several examples of proteins associated with the desensitization pathway are known in the art and described in the instant specification. For example, in paragraph [0042] of the published application, the "GPCR desensitization pathway" is described as including not only arrestin but also GRKs, GPCRs, AP-2 protein, clathrin, protein

phosphatases, as well as other molecules. In addition, conjugates of the invention are described in paragraphs [0107] through [0113] as including arrestins or GPCRs, including modified GPCRs.

As will be appreciated, an adequate written description of the invention "may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." MPEP \$2163. Applicants submit that the present specification provides sufficient identifying characteristics of the claimed invention to fulfill the written description requirement. Several different proteins that can function as a conjugate of the invention are described in sufficient detail to convey to one of skill in the art that the inventors were in possession of the invention at the time of filing. In addition, working examples of multiplex receptor assays utilizing exemplary conjugates are provided in the present specification. Together, the description and the examples of the present specification would convey to one of skill in the art that the inventors were at the time the present application was filed in possession of the claimed invention, and that this claimed invention includes conjugates comprising arrestin as well as other molecules, such as GPCRs and GRKs. As such, the present claims fully comply with the written description requirement of 35 USC. §112, first paragraph.

Furthermore, the test of enablement is whether one reasonably skilled in the art could make or use the invention as claimed from the disclosure in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). *See also* MPEP §2164.01. One way to determine if undue experimentation is required is to utilize the *Wands* factors: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." All of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

Applicants submit that the description of the different molecules associated with the GPCR desensitization pathway (as described above) coupled with the working examples of multiplex receptor assays using exemplary conjugates of the invention provides sufficient guidance such that the present application complies with the enablement requirement of 35 USC §112, first paragraph. The amount of direction or guidance presented is sufficient to allow one of skill in the art to practice the claimed invention without undue experimentation. As discussed above, the characteristics of the types of molecules that can be included in conjugates of the invention, as well as specific examples of components of these conjugates, are described in detail throughout the present specification. Since the types of molecules associated with the desensitization pathway are described in the specification and known in the art, one of skill in the art would readily understand the scope of the invention in terms of what kinds of conjugates can be used in accordance with the invention. Furthermore, the present specification provides working examples of multiplex receptor assays in which different conjugates are described and used to analyze different test compounds. One of skill in the art would therefore have sufficient guidance as to the creation and use of conjugates of the claimed invention – see for example, paragraphs [0118] through [0125]. As will be appreciated, although not every possible conjugate encompassed by the present claims is described in the working examples, Applicants respectfully submit that such description is not a requirement for enablement. The specification need not contain multiple working examples if the invention is otherwise disclosed in such a manner that one skilled in the art would be able to practice the invention without undue experimentation.¹ Furthermore, "In othing more than objective enablement is required, and therefore it is irrelevant whether [a] teaching is provided through broad terminology or illustrative examples."² One of skill in the art could use the description of the present specification to make and use any conjugate encompassed by the claims without undue experimentation. As such, Applicants respectfully submit that the enablement requirement of 35 USC §112, first paragraph is fully met by the present specification and claims.

¹ *In re Borkowski*, 164 USPQ at 645. ² *In re Robins* 166 USPQ 552 at 555 (CCPA 1970).

For at least the foregoing reasons, Applicants respectfully request that the rejections under 35 USC §112, first paragraph be withdrawn.

Rejections under 35 USC § 102(b)

Claims 61 to 73 are rejected under 35 USC 102(b) as allegedly being anticipated by Barak et al., U.S. Patent No. 5,891,646 ("Barak"). Applicants respectfully disagree.

To maintain a *prima facie* case of anticipation, the Office Action must demonstrate that each and every element as set forth in the claim is either expressly found or is inherently described in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the ...claim. *See MPEP § 2131*.

Applicants respectfully submit that every element of the instantly claimed invention is not described in Barak. Barak fails to describe or suggest a method of screening in which a cell comprises two different GPCRs and two different marker conjugates. Although Barak does describe cells that express multiple GPCRs, Barak does not describe or suggest any kind of method that is able to show which of the multiple GPCRs is affected by the test composition. As such, Barak fails to describe the claimed methods which utilize cells that comprise the elements of a first and second GPCR, where the second GPCR is different from the first GPCR, and a first and second conjugate, where the first conjugate includes a protein associated with the desensitization pathway of the first GPCR and the second conjugate includes a protein associated with the desensitization pathway of the second GPCR. Nor does Barak describe the elements of detecting a first and a second conjugate. The methods in Barak, even with cells expressing multiple GPCRs, cannot provide data that distinguishes the effect of a test composition among the different GPCRs. As such, Barak cannot describe every element of the presently claimed invention.

For at least the foregoing reasons, Barak fails to fulfill the requirements for a finding of anticipation under 35 USC §102(b). As such, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

While Applicants believe that no other fees are due at this time, the Commissioner is authorized to charge any fees, including extension fees or any other relief that may be required, in connection with this reply to Deposit Account 50-0310 (Docket No.: 067437-5021-US)

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-442-1266.

April 29, 2009

Respectfully submitted,

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DB2/21015102.2

Human G Protein Coupled Receptor Family (Receptors known as of January, 1999)

THERAPEITTICS		Acuity Alzheimer's		Diabetes, Cardiovascular	Cardiovascular, Respiratory	Anti-inflammatory Illogra	Depression, Insomnia, Analgesic	•	Cardiovascular Endocrine	Anti-inflammaton: A attune	Anti-inflammatony, Astuma	Anti-information;	Anti-inflammeters	Anti information.	Obesity	Airtigat Discours Amouttest:		Cardiovascular Desciretory	Anti-inflormation: And anti-inflormation	Determination of the control of the	Dellavior, Memory, Cardiovascular	Cardiovascular, Analgesic	Depression, Analgesic	Ottoology, Fazzaromici o
PHYSIOLOGY		Neurotransmitter		Gluconeogenesis	Neurotransmitter	Vascular Permeahility	Neurotransmitter		Vasoconstriction	Vasodilation	Immune System	Chemoattractant	Chemoattractant	Chemoattractant	Fat Metabolism	Bronchodilator Dain	Motility Fat Absorption	Muscle Contraction	Metabolic Remilation	Nemotransmitter	CNIC	SNS	Neurotransmitter	
TISSUE		Brain, Nerves, Heart		Brain, Kidney, Lung Kidney, Heart	Brain, Kidney, GI	Vascular, Heart, Brain	Most Tissues		Vascular, Liver, Kidney	Liver, Blood	Blood	Blood	Blood	Blood	Brain	Brain	Gastrointestinal	Heart, Bronchus, Brain	Kidney, Brain	Nerves, Intestine, Blood	Brain	Brain	Brain, Gastrointestinal	•
NUMBER		\$	V	D M	32	7	16	,	7		_	ന	₩	9	7		7	7	2	2		'n	5	
SS LIGAND	•Class I Rhodopsin like •Amine	•Acetylcholine (muscarinic & nicotinic)	•Adrenoceptors	Apria Amenoceptors Beta Adrenoceptors	•Doparnine	•Histamine	Serotonin (5-HT)Pentide		•Angiotensin	 Bradykinin 	 C5a anaphylatoxin 	•Fmet-leu-phe	•Interleukin-8	•Chemokine	•Orexin	•Nociceptin	•CCK (Gastrin)	•Endothelin	 Melanocortin 	•Neuropeptide Y	•Neurotensin	•Opioid	•Somatostatin	

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Depression, Analgesic Anti-coagulant, Anti-inflammatory Anti-diuretic, Diabetic Complications Analgesics, Alzheimer's	Infertility Infertility Thyroidism, Metabolism	Ophthalmic Diseases Olfactory Diseases	Cardiovascular, Analgesic Cancer, Anti-Inflammatory Cancer	Asthma, Rheumatoid Arthritis Cardiovascular Cardiovascular, Respiratory	Cardiovascular, Respiratory Cardiovascular, Respiratory	Anti-inflammatory, Anti-asthmatic	Prostate Cancer, Endometriosis	Metabolic Regulation Oncology, Alzheimer's Regulation of Circadian Cycle
Neurohormone Coagulation Water Balance Neurotransmitter	Endocrine Endocrine Endocrine	Photoreception Smell	Vasodilation, Pain Inflammation Cell proliferation	Inflammation Platelet Regulation Vasoconstriction	Multiple Effects Relaxes Muscle Analgesics. Memory	Inflammation	Reproduction	Thyroid Regulation Neuroendocrine Neuroendocrine
Brain Nerves Platelets, Blood Vessels Arteries, Heart, Bladder Brain, Pancreas	Ovary, Testis Ovary, Testis Thyroid	5 Eye 4(~1000) Nose	Arterial, Gastrointestinal Vessels, Heart, Lung Most Cells White Blood Cells,	Bronchus Arterial, Gastrointestinal Arterial, Bronchus	Vascular, Bronchus Vascular, Platelets Sensory Perception	Most Peripheral Tissues	Reproductive Organs, Pituitary	Pituitary, Brain Gastrointestinal Brain, Eye, Pituitary
к к 4 н		5 4(~10	1225	←	4 4 Brain	,	—	, , , , , , , , , , , , , , , , , , ,
 Tachykinin (Substance P, NKA₁) Thrombin Vasopressin-like Galanin Hormone protein 	•Follicle stimulating hormone •Lutropin-choriogonadotropic •Thyrotropin • (Rhod)opsin	•Opsin •Olfactory •Prostanoid	 Prostaglandin Lysophosphatidic Acid Sphingosine-1-phosphate Leukotriene 	•Prostacyclin •Thromboxane •Nucleotide-like	•Adenosine •Purinoceptors •Cannabis 2	 Platelet activating factor Gonadotropin-releasing hormone like 	•Gonadotropin-releasing hormone	•Thyrotropin-releasing hormone •Growth hormone-inhibiting factor •Melatonin

Obesity, Gastrointestinal Osteoporosis Stress, Mood, Obesity	Diabetes, Obesity Cardiovascular Cardiovascular, Diabetes, Obesity Growth Regulation	Osteoporosis Metabolic Regulation	Gastrointestinal	Hearing, Vision Mood Disorders Cataracts, GI Tumors
Digestion Calcium Resorption Neuroendocrine	Sugar/Fat Metabolism Gluconeogenesis Gluconeogenesis Neuroendocrine	Calcium Regulation Metabolism	Motility	Sensory Perception Neurotransmitter Calcium Regulation
1 Gastrointestinal, Heart 1 Bone, Brain Adrenal, Vascular, Brain	I Adrenals, Fat Cells Liver, Fat Cells, Heart I Pancreas, Stomach, Lung I Brain	l Bone, Kidney I Brain, Pancreas, Adrenals	l Gastrointestinal	7 Brain Brain Parathyroid, Kidney, GI Tract
ike •Secretin •Calcitonin •Corticotropin releasing factor/urocortin	•Gastric inhibitory peptide (GIP) •Glucagon 1 •Glucagon-like Peptide 1 (GLP-1) •Growth hormone-releasing hormone	•Parathyroid hormone •PACAP •Vasoactive intestinal		•Metabotropic Glutamate •GABA _B •Extracellular Calcium Sensing
•Class II Secretin like			·Class III	

1G. 2C

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FIG 3A

G protein-coupled receptors:

(Division into Class A Or Class B)

- 1. A1 adenosine receptor [Homo sapiens]. ACCESSION AAB25533
 NPIVYAF RIQKFRVIFL KIWNDHFRCQ PAPPIDEDLP EERPDD
 Class A (SEQ ID NO: 1)
- 2. adrenergic, alpha -1B-, receptor [Homo sapiens]. ACCESSION NP_000670
 npiiypc sskefkrafv rilgeqergr griffffff legeaytyrp wtrggslers qsrkdsldds gsclsgsqrt lpsaspspgy
 lgrgapppve lcafpewkap gallslpape ppgrrgrhds gplfffkllt epespgtdgg asnggceaaa dvangqpgfk
 snmplapgqf

Class A (SEQ ID NO: 2)

 adrenergic receptor alpha-2A [Homo sapiens]. ACCESSION AAG00447 npviytifn hdfrrafkki lergdrkriv

Class A (SEQ ID NO: 3)

- 4. alpha-2B-adrenergic receptor human. ACCESSION A37223
 npviytifn qdfrrafirri lcrpwtqtaw
 Class A (SEQ ID NO: 4)
- 5. alpha-2C-adrenergic receptor human. ACCESSION A31237 npviytvín qdírpsíkhi límmrgír q
 Class A (SEQ ID NO: 5)
- 6. beta-1-adrenergic receptor [Homo sapiens]. ACCESSION NP_000675
 npiiyers pdfrkafqgl lecarraarr rhathgdrpr asgelarpgp ppspgaasdd ddddvvgatp parllepwag
 enggaaadsd ssldeperpg faseskv

Class A (SEQ ID NO: 6)

7. beta-2 adrenergic receptor. ACCESSION P07550 npliyersp dfriafqell chrsslkay gngyssngnt 361 geqsgyhveq ekenkliced ipgtedfvgh qgtvpsdnid sqgrnestnd sli

Class A (SEQ ID NO: 7)

8. dopamine receptor D1 [Homo sapiens]. ACCESSION NP_000785
npii yafnadfrka fstilgcyrl cpatmaiet vsinnngaam fsshheprgs iskecnlvyl iphavgssed lkkeeaagia
rpleklspal svildydtdv slekiqpitq ngqhpt

Class A (SEQ ID NO: 8)

D(2) dopamine receptor. ACCESSION P14416
 npiiyttfn iefrkaflki lhc

Class A (SEQ ID NO: 9)

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FIG 3B

d3 dopamine receptor - human. ACCESSION G01977
 np viyttfnief rkafikilse

Class A (SEQ ID NO: 10)

11. dopamine receptor D4 - human. ACCESSION DYHUD4 npviytv fnaefinvfr kalracc

Class A (SEQ ID NO: 11)

12. dopamine receptor D5 - human. ACCESSION DYHUD5 npviya fnadfqkvfa qllgcshfcs rtpvetvnis nelisynqdi vfhkeiaaay ihmmpnavtp gnrevdndee egpfdrmfqi yqtspdgdpv aesvweldce geisldkitp ftpngfh

Class A (SEQ ID NO: 12)

13. muscarinic acetylcholine receptor M1 [Homo sapiens]. ACCESSION NP_000729 npmcyal cnkafrdtfr llllcrwdkr rwrkipkrpg svhrtpsrqc

Class A (SEQ ID NO: 13)

 muscarinic acetylcholine receptor M2 [Homo sapiens]. ACCESSION NP_000730 npacy alcnatfkkt fkhllmchyk nigatr

Class A (SEQ ID NO: 14)

- 15. muscarinic acetylcholine receptor M3 [Homo sapiens]. ACCESSION NP_000731 n pveyalenkt fittfkmlll eqedkkkrik qqyqqrqsvi fikrapeqal Class A (SEQ ID NO: 15)
- 16. muscarinic acetylcholine receptor M4 [Homo sapiens]. ACCESSION NP_000732 npa cyalcnatfk ktfrhllleq ymigtar

Class A (SEQ ID NO: 16)

17. m5 muscarinic receptor. locus HUMACHRM ACCESSION AAA51569 npicyalcnr tfrktfkmll lcrwkkkkve eklywqgnsk lp
Class A (SEQ ID NO: 17)

18. 5-hydroxytryptamine (serotonin) receptor 1A [Homo sapiens]. ACCESSION BAA90449 npviy ayfnkdfqna fkkiikckf

Class A (SEQ ID NO: 18)

5-hydroxytryptamine (serotonin) receptor 1B [Homo sapiens]. ACCESSION BAA94455
 npiiyt msnedfkqaf hklirfkcts

Class A (SEQ ID NO: 19)

20. 5-hydroxytryptamine (serotonin) receptor 1E [Homo sapiens]. ACCESSION BAA94458 n pllytsfined fklafkklir cre

Class A (SEQ ID NO: 20)

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FIG 3C

- 21. OLFACTORY RECEPTOR 6A1. ACCESSION 095222
 npiiyclrnq evkralccil hlyqhqdpdp kkgsrnv
 Class A (SEQ ID NO: 21)
- 22. OLFACTORY RECEPTOR 2C1. ACCESSION 095371
 npliy tirnmevkga hrllgkgre vg
 Class A (SEQ ID NO: 22)
- 23. angiotensin receptor 1 [Homo sapiens]. ACCESSION NP_033611 npl fygfigkkfk ryfiqllkyi ppkakshsnl sfkmsflsyr psdnvssstk kpapcfeve Class B (SEQ ID NO: 23)
- 24. angiotensin receptor 2 [Homo sapiens]. ACCESSION NP_000677 npflycf vgnrfqqklr svfivpitwl qgkresmscr kssslremet fvs Class B (SEQ ID NO: 24)
- 25. interleukin 8 receptor beta (CXCR2) [Homo sapiens]. ACCESSION NM_001557 NPLIYAFIGQKFRHGLLKILAIHGLISKDSLPKDSRPSFVGSSSGHTSTTL Class B (SEQ ID NO: 25)
- 26. cx3c chemokine receptor 1 (cx3cr1) (fractalkine receptor) ACCESSION P49238 np liyafagekf rrylyhlygk clavlcgrsv hvdfsssesq rsrhgsvlss nftyhtsdgd allll Class B (SEQ ID NO: 26)
- 27. neurotensin receptor human. ACCESSION S29506
 n pilynlysan fihiflatla clcpywmr krpafsrkad syssnhflss natretly
 Class B (SEQ ID NO: 27)
- 28. SUBSTANCE-P RECEPTOR (SPR) (NK-1 RECEPTOR) (NK-1R). ACCESSION P25103 npiiyoclnd rfrlgfkhaf recpfisagd yeglemkstr ylqtqgsvyk vsrletfistvvgaheeepe dgpkatpssl dltsncssrs dsktmtesfs fssnvls

 Class B (SEQ ID NO: 28)
- vasopressin receptor type 2 [Homo sapiens]. ACCESSION AAD16444
 npwiyasfss sysselrsll ccargrtpps lgpqdesctt assslakdts s
 Class B (SEQ ID NO: 29)
- 30. thyrotropin-releasing hormone receptor human. ACCESSION JN0708 npviy nlmsqkfraa frklcnckqk ptekpanysv alnysvikes dhfstelddi tvtdtylsat kvsfddtcla sevsfsqs Class B (SEQ ID NO: 30)

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FIG 3D

- 31. oxytocin receptor human. ACCESSION A55493
 npwiym lftghlfhel vqrflccsas ylkgrrlget saskksnsss fvlshrsssq rscsqpsta
 Class B (SEQ ID NO: 31)
- 32. neuromedin U receptor [Homo sapiens]. ACCESSION AAG24793
 npvlyslmssrfretfqealclgacchrlrprhsshslsrmttgstlcdvgslgswvhplagndgpeaqqetdps
 Class B (SEQ ID NO: 32)
- 33. gastrin receptor. ACCESSION AAC37528
 nplvy cfmhrrfrqa eleteareep rpprarpral pdedpptpsi aslsrlsytt istlgpg
 Class B (SEQ ID NO: 33)
- 34. galanin receptor 3 [Homo sapiens]. ACCESSION 10879541
 nplv yalasrhfra rfirrlwpcgr rrthrarral rrvrpassgp pgcpgdarps grllagggqg pepregpvhg geaargpe
 Class A (SEQ ID NO: 34)
- 35. edg-1 human. ACCESSION A35300

 npiiy tltnkemrra firimsceke psgdsagkfk rpiiagmefs rskådnsshp 361 qkdegdnpet imssgnvnss s

 Class A (SEQ ID NO: 35)
- 36. central cannabinoid receptor [Homo sapiens]. ACCESSION NP_057167 npiiyalr skdlrhafrs mfpscegtaq pldnsmgdsd clhkhannaa svhraaesci kstvkiakvt msvstdtsae al Class A (SEQ ID NO: 36)
- delta opioid receptor human. ACCESSION I38532
 npvlyaf ldenfkrefr qlerkpegrp dpssfsrpre atarervtac tpsdgpgggr aa
 Class A (SEQ ID NO: 37)
- 38. proteinase activated receptor 2 (PAR-2) human. ACCESSION P55085 dpfvyyfvshdfrdhaknallcrsvrtvkqmqvsltskkhsrksssyssssttvktsy
 Class A (SEQ ID NO: 38)
- 39. vasopressive intestinal peptide receptor (VIPR) rat. ACCESSION NM_012685
 NGEVQAELRRKWRRWHLQGVLGWSSKSQHPWGGSNGATCSTQVSMLTRVSPSARR
 SSSFQAEVSLV

Class B (SEQ ID NO: 39)